HAND SANITIZER- alcohol gel HAND SANITIZER- alcohol liquid HAND SANITIZER WIPES- alcohol cloth Horizon Tool Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

#### Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

#### **Purpose**

Antiseptic, Hand Sanitizer

#### Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

#### Warnings

For external use only. Flammable. Keep away from heat or flame

#### Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

#### Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

#### **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

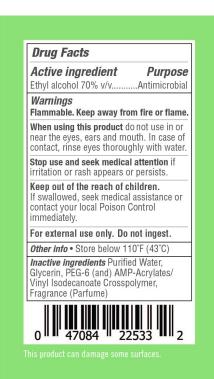
#### Package Label - Principal Display Panel

59 mL NDC: 74683-2100-1



Drug Facts	2262
Active ingredient Pu	Purpose
Ethyl alcohol 80% v/vAntimicrobial	crobial
Warnings	
Flammable. Keep away from fire or	
flame.	
When using this product do not use in or	in or
near the eyes. In case of contact, rinse	se
eyes thoroughly with water.	
Stop use and seek medical attention if	n if
irritation or rash appears or persists.	
Keep out of the reach of children.	
If swallowed, seek medical assistance or	_
contact your local Poison Control immediately.	diately.
For external use only. Do not ingest.	. :
Other info • Store below 110°F (43°C)	
Inactive ingredients Glycerin, Hydrogen	gen
Peroxide, Purified Water USP	
* This product can damage some surfaces	ces
AllShield . • 7918 Industrial Village Road • Greensboro,	nsboro,
NC 27409 • Questions? 833-307-0523	

946.35 mL NDC: 74683-3001-1





Apply product to your har rub together vigorously.

Allow them to air dry.

Avoid wiping your hands

Distributed by Horizon Tool, Incorpora 7918 Industrial Village Road.

Greensboro NO 27400

ALLSHIELD HAND SANITIZER

Made in USA

Ts

262 mL NDC: 74683-2500-1



1892.71 mL NDC: 74683-5000-9





Directions for use:

Apply product to your hands and rub together vigorously. Allow them to air dry.

Avoid wiping your hands dry.

\*This product can damage certain surfaces.

Distributed by Horizon Tool, Incorporated 7918 Industrial Village Road, Greensboro, NC 27409 www.allshieldusa.com Questions? 833-307-0523 Made in USA

EXP 1/2023



208.2 L NDC: 74683-5000-8





Directions for use (a Apply product to your h Allow them to air dry. Avoid wiping your hand If using on a hard surfa inconspicuous area.

If pleased, with the res

#### Drug Facts

Active ingredient

Warning

Flammable. Keep away from fin When using this product do not contact, rinse eyes thoroughly v Stop use and seek medical atte Keep out of the reach of childre your local Poison Control imme For external use only. Do not in Other Info \* Store below 110°F (\* Inactive Ingredients Purified W Vinyl Isodecanoate Crosspolym

\*This product can damage

Distributed by Horizon Tool, 7918 Industrial Village Roa Greensboro, NC 27409

Questions? Call 1(833)307 visit www.allshieldusa.com

Made in USA



946.35 mL NDC: 74683-5000-7



#### **Drug Facts**

#### Active ingredient

**Purpose** 

Ethyl alcohol 70% v/v......Antimicrobial

#### Warnings

Flammable. Keep away from fire or flame.

When using this product do not use in or near the eyes, ears and mouth. In case of contact, rinse eyes thoroughly with water.

Stop use and seek medical attention if irritation or rash appears or persists.

Keep out of the reach of children. If swallowed, seek medical assistance or contact your local Poison Control immediately.

For external use only. Do not ingest.

Other info • Store below 110°F (43°C)

Inactive ingredients Purified Water, Glycerin, PEG-6 (and) AMP-Acrylates/ Vinyl Isodecanoate Crosspolymer, Fragrance (Parfume)

This product can damage certain surfaces.



#### **Directions for use:**

Apply product to your hands and rub together vigorously. Allow them to air dry. Avoid wiping your hands dry.

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www.allshieldusa.com

Questions? 1-833-307-0523

Made in USA

EXP 1/2023

946.35 mL NDC: 74683-5000-7



# EXCEEDS THE CDCs RECOMMENDED ALCOHOL STRENGTH

32 FL. OZ. (946.35 ML)

473 mL NDC: 74683-5000-6

#### **Drug Facts**

Active ingredient

**Purpose** 

Ethyl alcohol 70% v/v.....Antimicrobial

#### Warnings

Flammable. Keep away from fire or flame.

When using this product do not use in or near the eyes, ears and mouth. In case of contact, rinse eyes thoroughly with water.

Stop use and seek medical attention if irritation or rash appears or persists.

Keep out of the reach of children. If swallowed, seek medical assistance or contact your local Poison Control

immediately. For external use only. Do not ingest.

Other info • Store below 110°F (43°C)

Inactive ingredients Purified Water, Glycerin, PEG-6 (and) AMP-Acrylates/ Vinyl Isodecanoate Crosspolymer, Fragrance (Parfume)





**PROUDLY** MADE IN THE USA



EXCEEDS THE CDCs RECOMMENDED ALCOHOL STRENGTH



#### **Directions for use:**

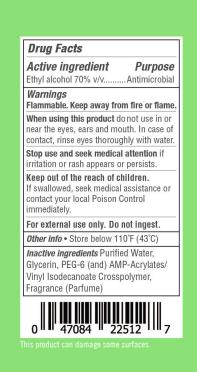
3785.41 mL NDC: 74683-5000-5



3785.41 mL NDC: 74683-5000-4



354.8 mL NDC: 74683-5000-3





Item# 22512



#### **Directions for use:**

Apply product to your hands and rub together vigorously.

Allow them to air drv.

Avoid wiping your hands dry.

Distributed by Horizon Tool, Incorporated 7918 Industrial Village Road.

www.allshieldusa.com Questions? 833-307-0523

n USA EXP 1/202

236 mL NDC: 74683-5000-2





8 FL OZ (236 ML)



#### **Directions for use:**

Apply product to your hands and rub together vigorously.

Allow them to air dry.

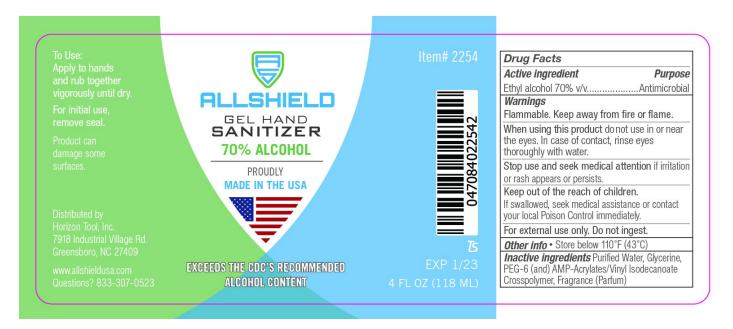
Avoid wiping your hands dry

Distributed by Horizon Tool, Incorporated 7918 Industrial Village Road. Greenshord, NC 27409

www.allshieldusa.com Questions? 833-307-0523

EXP 1/20

118 mL NDC: 74683-5000-1



118 mL NDC: 74683-4000-1



Drug Fac
Active Ingi
Ethyl alcoho
Warnings
Flammable.
When using
the eyes. In
thoroughly v
Stop use ar
or rash appe
Keep out of
If swallowed,
your local Po
For externa
Other Info
Inactive In
Copolymer, 6

3 mL NDC 74683-3000-8

# **Drug Facts**

# Active ingredient

**Purpose** 

Ethyl alcohol 70%...... Antimicrobial

# Warnings

Flammable. Keep away from fire or flame.

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and seek medical attention if irritation or rash appears or persists.

Keep out of the reach of children. If swallowed, seek medical assistance or contact Poison Control immediately.

For external use only. Do not ingest.

Other info • Store below 110°F (43°C)

**Inactive ingredients** Purified Water, Acrylates Copolymer, Gylcerine, Amino Methyl Propanol

For instant use without water: Apply to hands and rub together vigorously until dry.

Distributed by Horizon Tool, Inc.

7918 Industrial Village Road Greensboro, NC 27409

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Questions? 1-833-307-0523

Made in the USA

EXP

7/23



3 mL NDC 74683-3000-9

\_..........

# Active ingredient

**Purpose** 

Ethyl alcohol 75% ± 5% v/v..... Antimicrobial

Warnings

Flammable. Keep away from fire or flame.

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and seek medical attention if irritation or rash appears or persists.

Keep out of the reach of children.

If swallowed, seek medical assistance or contact your local Poison Control immediately.

For external use only. Do not ingest.

Other info • Store below 110°F (43°C)

Inactive ingredients Water, Carbomer,

Triethanolamine

This product can damage some surfaces.

For instant use without water: Open packet, apply to hands and rub together vigorously until dry.

Distributed by Horizon Tool, Inc. 7918 Industrial Village Road Greensboro, NC 27409

Questions? 1-833-307-0523

EXP 7/23

Made in China.



# GEL HAND SANITIZER SINGLE USE

75% ALCOHOL



EXCEEDS THE CDC'S RECOMMENDED
ALCOHOL CONTENT

# 0.1 FL OZ (3 ML)

#### 3785.41 mL NDC 74683-3000-7



#### 3785.41 mL NDC 74683-3000-6



3785.41 mL NDC 74683-3000-5



#### 1892.71 mL NDC 74683-3000-4



946.35 mL NDC 74683-3000-3



#### **Drug Facts**

#### Active ingredient

**Purpose** 

Ethyl alcohol 70% v/v......Antimicrobial

#### **Warnings**

Flammable. Keep away from fire or flame.

When using this product do not use in or near the eyes, ears and mouth. In case of contact, rinse eyes thoroughly with water.

Stop use and seek medical attention if irritation or rash appears or persists.

Keep out of the reach of children. If swallowed, seek medical assistance or contact your local Poison Control immediately.

For external use only. Do not ingest.

Other info • Store below 110°F (43°C)

Inactive ingredients Purified Water, Acrylates Copolymer, Glycerin, Amino Methyl Propanol

This product can damage certain surfaces.



#### **Directions for use:**

Apply product to your hands and rub together vigorously. Allow them to air dry. Avoid wiping your hands dry.

Distributed by Horizon Tool, Incorporated 7918 Industrial Village Road, Greensboro, NC 27409

www.allshieldusa.com

Questions? 1-833-307-0523

Made in USA

EXP 11/2022

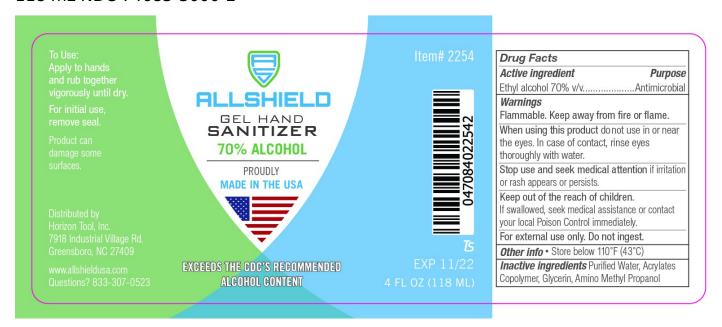
946.35 mL NDC 74683-3000-3



# EXCEEDS THE CDCs RECOMMENDED ALCOHOL STRENGTH

32 FL. OZ. (946.35 ML)

#### 118 mL NDC 74683-3000-2



# **Drug Facts**

# Active ingredient

**Purpose** 

Ethyl alcohol 70% v/v..... Antimicrobial

# Warnings

Flammable. Keep away from fire or flame.

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and seek medical attention if irritation or rash appears or persists.

Keep out of the reach of children.

If swallowed, seek medical assistance or contact your local Poison Control immediately.

For external use only. Do not ingest.

Other info • Store below 110°F (43°C)

**Inactive ingredients** Purified Water, Acrylates Copolymer, Glycerin, Amino Methyl Propanol

This product can damage some surfaces.

Distributed by Horizon Tool, Inc. 7918 Industrial Village Road Greensboro, NC 27409

Questions? 1-833-307-0523

EXP 11/22

Ts



2252



# ALLSHIELD

# SANITIZER

70% ALCOHOL

PROUDLY MADE IN THE USA

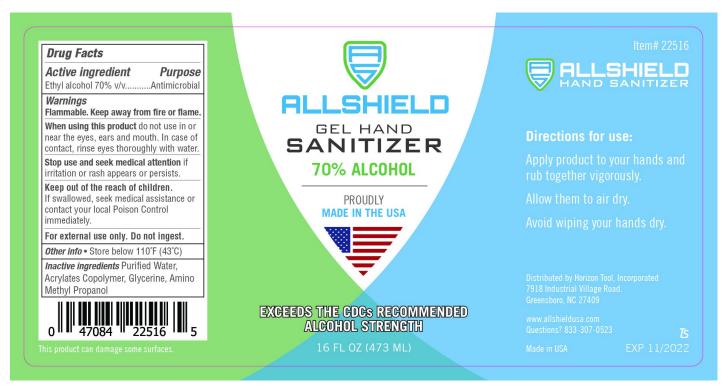


EXCEEDS THE CDC'S RECOMMENDED
ALCOHOL CONTENT

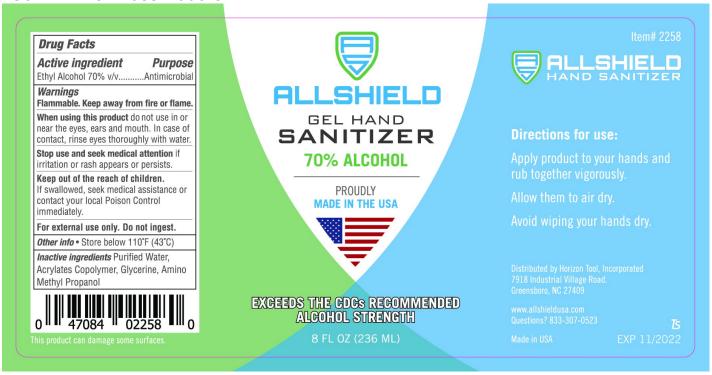
Easy to Use: Apply to hands and rub together vigorously until dry

2 FL OZ (59 ML)

#### 473 mL NDC 74683-1000-9



#### 236 mL NDC 74683-1000-8



059 mL NDC: 74683-1000-6





059 mL NDC: 74683-1000-6

# **Drug Facts**

# Active ingredient

**Purpose** 

Ethyl alcohol 70% v/v.....Antimicrobial

# **Warnings**

Flammable. Keep away from fire or flame.

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and seek medical attention if irritation or rash appears or persists.

Keep out of the reach of children.

If swallowed, seek medical assistance or contact your local Poison Control immediately.

For external use only. Do not ingest.

Other info • Store below 110°F (43°C)

Inactive ingredients Glycerin, Hydroxypropyl Cellulose, Purified Water USP

This product can damage some surfaces.

Distributed by Horizon Tool, Inc. 7918 Industrial Village Road Greensboro, NC 27409

EXP 10/22



#### 74683-1000-7

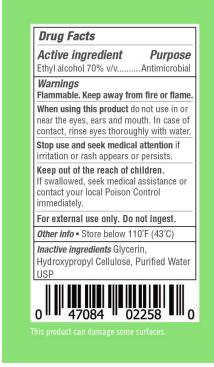




**Drug Facts** Active ingredient Purpose Ethyl alcohol 70% v/v.....Antimicrobial Warnings Flammable. Keep away from fire or flame. When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. Stop use and seek medical attention if irritation or rash appears or persists. Keep out of the reach of children. If swallowed, seek medical assistance or contact your local Poison Control immediately. For external use only. Do not ingest.

Other info • Store below 110°F (43°C) Inactive ingredients Glycerin, Hydroxypropyl Cellulose, Purified Water USP

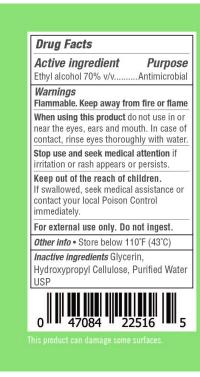
236 mL NDC: 74683-2000-1





#### **Directions for use:**

473 mL NDC: 74683-1000-2







#### Directions for use:

Apply product to your hands and rub together vigorously.

Allow them to air dry.

Avoid wiping your hands dry

Distributed by Horizon Tool, Incorporated 7918 Industrial Village Road.

Greenshoro, NC 27409

Made in USA

EXP 09/2022

946.35 mL NDC: 74683-1000-3



EXCEEDS THE CDCs RECOMMENDED ALCOHOL STRENGTH

32 FL. OZ. (946.35 ML)

946.35 mL NDC: 74683-1000-3



Drug Facts	
Active ingredient	Purpose
Ethyl alcohol 70% v/v	Antimicrobial
Warnings Flammable. Keep away from fire or flame.	
When using this product do not use in or near the eyes, ear of contact, rinse eyes thoroughly with water.	rs and mouth. In case
Stop use and seek medical attention if irritation or rash ap	pears or persists.
<b>Keep out of the reach of children.</b> If swallowed, seek med contact your local Poison Control immediately.	dical assistance or
For external use only. Do not ingest.	
Other info • Store below 110°F (43°C)	
Inactive ingredients Glycerin, Hydroxypropyl Cellulose, Po	urified Water USP

## **Directions for use:**

Apply product to your hands and rub together vigorously. Allow them to air dry. Avoid wiping your hands dry.

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Made in USA

EXP 09/2022



1892.71 mL NDC: 74683-1000-4

This product can damage certain surfaces.





#### Directions for use:

Apply product to your hands and rub together vigorously. Allow them to air dry. Avoid wiping your hands dry.

Drug Facts	
Active ingredient	Purpose
Ethyl alcohol 70% v/v	Antimicrobia
Warnings Flammable. Keep away from fire or flame.	
When using this product do not use in or near the eye of contact, rinse eyes thoroughly with water.	s, ears and mouth. In case
Stop use and seek medical attention if irritation or ra	sh appears or persists.
Keep out of the reach of children. If swallowed, seek contact your local Poison Control immediately.	medical assistance or
For external use only. Do not ingest.	
Other info • Store below 110°F (43°C)	
Inactive ingredients Glycerin, Hydroxypropyl Cellulo	ose, Purified Water USP

\*This product can damage certain surfaces.

EXP 09/2022

Distributed by Horizon Tool, Incorporated
7918 Industrial Village Road,
Greensboro, NC 27409
Made in USA
47084
22564

3785.41 mL NDC: 74683-1000-5



473 mL NDC: 74683-2000-1

ALLSHIELD HAND SANITIZER

Active ingredient Ethyl alcohol 70% v/v.... Purpose Other Info • Store below 110°F (43°C)
Inactive Ingredients Glycerin, Hydroxypropyl Cellulose, Purified Water USP

\*This product can damage certain surfaces.

EXP 09/2022

Distributed by Horizon Tool, Incorporated 7918 Industrial Village Road, Greensboro, NC 27409 Made in USA





473 mL NDC: 74683-2000-1



946.35 mL NDC: 74683-2000-2



946.35 mL NDC: 74683-2000-2



#### **Drug Facts**

#### Active ingredient

**Purpose** 

Isopropyl alcohol 80% v/v......Antimicrobial

#### Warnings

Flammable. Keep away from fire or flame

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and seek medical attention if irritation or rash appears and lasts.

Keep out of the reach of children.

For external use only. Do not ingest. If swallowed, seek medical assistance or contact your local Poison Control immediately.

Other info • Store below 110°F (43°C)

Inactive ingredients Water (Aqua)

#### **Directions for use:**

Apply product to your hands.

Rub them together vigorously.

Allow them to air dry.

Avoid wiping your hands dry.

If using on a hard surface\*, begin by testing a small inconspicuous area.

If pleased, with the results, spray and wipe dry or let air dry.

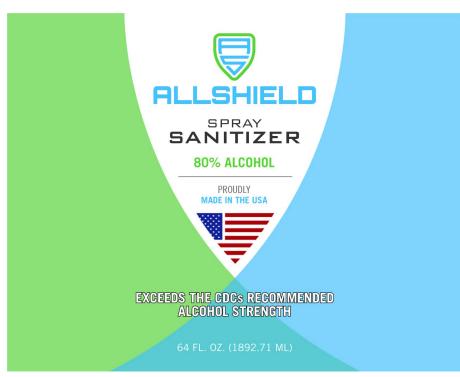
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Made in USA



EXP 09/2022

1892.71 mL NDC: 74683-2000-3





Item# 22664

#### Directions for use:

Apply product to your hands and rub together vigorously.

Allow them to air dry.

Avoid wiping your hands dry.

If using on a hard surface\*, begin by testing on a small inconspicuous area. If pleased, with the results, spray and wipe dry or let air dry.

Drug Facts	
Active ingredient	Purpose
Ethyl alcohol 80% v/v	Antimicrobia
Warnings Flammable. Keep away from fire or flame.	
When using this product do not use in or near the eyes of contact, rinse eyes thoroughly with water.	, ears and mouth. In case
Stop use and seek medical attention if irritation or ras	h appears or persists.
Keep out of the reach of children. If swallowed, seek of contact your local Poison Control immediately.	medical assistance or
For external use only. Do not ingest.	
Other info • Store below 110°F (43°C)	
Inactive ingredients Glycerin, Hydrogen Peroxide, Pu	rified Water USP

This product can damage certain surfaces

EXP 09/2022

Distributed by Horizon Tool, Incorporated 7918 Industrial Village Road, Greensboro, NC 27409 Made in USA



3785.41 mL NDC: 74683-2000-4

<sup>\*</sup> This product can damage certain surfaces.





#### Directions for use:

Directions for use:
Apply product to purhands and rub together vigorously.
Allow them to air dry.
Avoid wijning your hands dry.
If using on a hard surface, begin by testing on a small inconspicuous area.
If pleased, with the results, spray and wipe dry or let air dry.

Drug Facts Active ingredient

Ethyl alcohol 80% vv...

Warnings
Flammable. Keep away from fire or flame.

When using this product do not use in or near the eyes, ears and mouth. In case of contact, mixe eyes thoroughly with water.

Stop use and seek medical altention if intradian or rash appears or persists.

Keep out of the reach of children. If swallowed, seek medical assistance or contact your local Poison Control immediately.

For external use only, bo not linges.

Other Info • Store below 110°F (43°C)

Inactive Ingredients Glycerin, Hydrogen Peroxide, Purified Water USP

\*This product can damage certain surfaces.

EXP 09/2022

Purpose

Distributed by Horizon Tool, Incorporated 7918 Industrial Village Road, Greensboro, NC 27409 Made in USA



#### **HAND SANITIZER**

alcohol gel

#### **Product Information**

**Product Type** HUMAN OTC DRUG **Item Code (Source)** NDC:74683-5000

**Route of Administration TOPICAL** 

#### **Active Ingredient/Active Moiety**

**Ingredient Name Basis of Strength** Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII: 3K9958V90M) 715.4 mL in 1021.95 mL ALCOHOL

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)	282 mL in 1021.95 mL			
RAPIDGEL EZ1 (UNII: 33JH4A7R2K)	9.7 mL in 1021.95 mL			
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)	0.044 mL in 1021.95 mL			
DENATONIUM BENZOATE ANHYDROUS (UNII: M5BA6GAF10)	0.006 mL in 1021.95 mL			
GLYCERIN (UNII: PDC6A3C0OX)	14.8 mL in 1021.95 mL			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74683- 5000-1	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/11/2020	
2	NDC:74683- 5000-2	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/11/2020	
3	NDC:74683- 5000-3	354.8 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/11/2020	
4	NDC:74683- 5000-4	3785.41 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/11/2020	

5	NDC:74683- 5000-5	3785.41 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/11/2020	
6	NDC:74683- 5000-6	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/11/2020	
7	NDC:74683- 5000-7	946.35 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/11/2020	
8	NDC:74683- 5000-8	208200 mL in 1 DRUM; Type 0: Not a Combination Product	11/11/2020	
9	NDC:74683- 5000-9	1892.71 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/11/2020	

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
OTC monograph not final	part333A	11/11/2020		

alcohol gel

Product Information			
Product Type HUMAN OTC DRUG Item Code (Source) NDC:74683-3000			
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	73 mL in 100 mL		

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL			
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL			
WATER (UNII: 059QF0KO0R)				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:74683- 3000-1	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/17/2020		
2	NDC:74683- 3000-2	118 mL in 1 BLISTER PACK; Type 0: Not a Combination Product	07/17/2020		
3	NDC:74683- 3000-3	946.35 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/17/2020		
4	NDC:74683- 3000-4	1892.71 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/17/2020		

5	NDC:74683- 3000-5	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/17/2020	
6	NDC:74683- 3000-6	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/17/2020	
7	NDC:74683- 3000-7	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/17/2020	
8	NDC:74683- 3000-9	3 mL in 1 POUCH; Type 0: Not a Combination Product	07/17/2020	
9	NDC:74683- 3000-8	3 mL in 1 POUCH; Type 0: Not a Combination Product	07/17/2020	

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
OTC monograph not final	part333A	07/17/2020		

alcohol gel

Product Information			
Product Type HUMAN OTC DRUG Item Code (Source) NDC:74683-1000			
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	73 mL in 100 mL	

Inactive Ingredients				
Ingredient Name	Strength			
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL			
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:74683- 1000-1	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020		
2	NDC:74683- 1000-2	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020		
3	NDC:74683- 1000-3	946.35 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020		
4	NDC:74683- 1000-4	1892.71 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020		

5	NDC:74683- 1000-5	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
6	NDC:74683- 1000-6	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
7	NDC:74683- 1000-7	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
8	NDC:74683- 1000-8	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2020	
9	NDC:74683- 1000-9	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2020	

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
OTC monograph not final	part333A	04/24/2020		

alcohol liquid

Product Information			
Product Type HUMAN OTC DRUG Item Code (Source) NDC:74683-2000			
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL	

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL			
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:74683- 2000-1	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020		
2	NDC:74683- 2000-2	946.35 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020		
3	NDC:74683- 2000-3	1892.71 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020		
4	NDC:74683- 2000-4	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/24/2020		

alcohol gel

#### **Product Information**

**Product Type** HUMAN OTC DRUG Item Code (Source) NDC:74683-4000

**Route of Administration TOPICAL** 

#### **Active Ingredient/Active Moiety**

**Basis of Strength Ingredient Name** Strength

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII: 3K9958V90M) ALCOHOL 73 mL in 100 mL

#### **Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL

### Packaging

ı	-				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:74683- 4000-1	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/24/2020	

## **Marketing Information**

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph not final	part333A	09/24/2020	

#### **HAND SANITIZER WIPES**

alcohol cloth

#### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74683-2500
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)	0.0145 mL in 100 mL		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.00125 mL in 100 mL		
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)	0.01 mL in 100 mL		
WATER (UNII: 059QF0KO0R)	0.27425 mL in 100 mL		

l	P	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1	NDC:74683- 2500-1	262 mL in 1 CANISTER; Type 0: Not a Combination Product	11/13/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	11/13/2020		

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74683-3001	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	73 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	

WATER (UNII: 059QF0KO0R)			
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL		

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	946.35 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/08/2021			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/08/2021		

alocohl liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74683-2100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL			
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL			

F	Packaging					
#	tem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:74683- 2100-1	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2021			

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/13/2021	

# Labeler - Horizon Tool Inc. (602012460)

Establishment				
Name	Address	ID/FEI	Business Operations	
TenSan		027499464	manufacture(74683-1000, 74683-2000, 74683-3000, 74683-4000, 74683-5000, 74683-3001)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Surry Chemicals, Inc.		083630285	manufacture(74683-1000, 74683-2000, 74683-3000)	

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Huizhou Baozi Biotechnology Co., Ltd.		419304583	manufacture(74683-3000)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Horizon Tool Inc.		602012460	repack(74683-1000, 74683-2000, 74683-3000, 74683-4000, 74683-5000), manufacture(74683-2500)	

Establishment			
Name	Address	ID/FEI	Business Operations
DuBois Chemicals, Inc.		828235445	manufacture(74683-2100)

Revised: 4/2021 Horizon Tool Inc.